REMARKS

Claims 1, 5, 6, 8, 11 and 14–17 are pending in the application. Claims 1, 8 and 11 have been amended. Support for the amendment can be found in the specification as originally filed. No new matter has been added.

REJECTIONS UNDER 35 USC 103

Claims 1-3, 5, 6, 8, 10, 11 and 14–17 stand rejected under 35 USC 103(a) as being unpatentable over Runnells et al. (US 3,752,145) in view of Niehoff (US 5,662,612). This rejection should be withdrawn in view of the remarks and amendments made herein.

It is well settled that to establish a *prima facie* case of obviousness, the USPTO must satisfy all of the following requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification does not have a reasonable expectation of success, as determined from the vantage point of one of ordinary skill in the art at the time the invention was made. *Amgen v. Chugai Pharmaceutical Co*. 18 USPQ 2d 1016, 1023 (Fed Cir, 1991), *cert. denied* 502 U.S. 856 (1991). Third, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496, (CCPA 1970).

The Office Action alleges that Runnells teaches a method of operating an injector, including that a "tube is then attached to the outlet 22 of the syringe and the free end of the tube is submerged in contrast solution. Air is bled from the syringe by advancing the piston plate 14 toward the outlet 22. Additional contrast solution may then be drawn through the tube into the syringe housing by retracting the piston plate." Further, the Office Action alleges that "Niehoff discloses a power injector which automatically senses the presence and capacity of a syringe and advances and retracts the plunger automatically (see Abstract)."

Applicants' invention of Claim 1 has been amended to include subject matter of "automatically advancing, without operator input, the piston to prime the syringe and a tube connected to the syringe." The novel aspects of Applicants' invention include that the piston primes not only the syringe, but also the tube without operator input. Specifically, Applicants' invention includes that:

> [the] "auto prime" feature allows an injector to automatically prime the fluid path (i.e., syringe and connecting tubing) before an injection procedure. Preferably, the volume of fluid contained within a connector tubing used with a syringe is pre-programmed into the injector. For example, a 60' low pressure connecting tubing ("LPCT") provided by Medrad, Inc., the Assignee of the present application, for use with its disposable syringes typically holds approximately 2.78 ml of fluid. Alternately, the operator may manually program the fluid volume contained within the connector tube into the injector.
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> As will become apparent, the auto prime feature may be functionally dependent, in certain respects, on the auto fill feature described above. When a syringe is filled with fluid (i.e., by means of the auto fill feature), the injector automatically compensates for the connector tube by adding its corresponding fluid volume to the fluid volume desired by the operator to be aspirated into the syringe for an injection operation. For example, if the operator desires to fill the syringe with 150ml of fluid for an injection procedure, the auto fill feature will compensate for the connector tube fluid volume by automatically adding 2.78 ml of fluid (e.g., for a 60' LPCT), for a total volume of 152.78 ml aspirated into the syringe. After the syringe is filed with fluid, the auto prime feature would then cause the injector piston to advance the syringe plunger to the extent necessary to expel air from the syringe and connector tube system, preferably without prompting by the operator. Once the auto prime function is conducted, fluid should be present at the patient end of the connector tube (i.e., the end that is connected to the catheter).
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> As can be appreciated, the auto prime feature may save operator time and reduce the amount of wasted fluid. By automatically compensating for the fluid contained within the connector tube, the operator does not have to vigilantly watch the progression of the fluid from the syringe through the connecting tube in order to stop the advancement of the piston before a significant amount of fluid is discharged from the end of the connector tubing. Also, because some operators of conventional injectors advance the piston quickly to lessen the time required to prime the syringe and tubing system, often a significant amount of fluid will be expelled from the end of the connector tubing before the operator stops the piston's advancement. If a sufficient amount of contrast is expelled, the syringe may have to be re-filled (and the syringe and tubing system subsequently re-primed) to insure that it contains a sufficient amount of fluid for

the required injection procedure.

> While the auto prime feature is preferably intended for use with empty syringes that have been filled with fluid by an aspiration procedure on the injector (i.e., non-prefilled and non-preloaded syringes), the auto prime feature could also be used with prefilled and preloaded syringes. (Page 59, Para 2 to page 59, para 2).

Neither Runnells nor Niehoff, either alone or in combination, provide a method of automatically advancing, without operator input, the piston to prime either the syringe or the tube connected to the syringe. Specifically, Runnells requires operator input. A magnification head 40 provides a safety chamber which captures and retains a residual portion of the contrast dye or other solution even when the piston plate 14 is fully advanced toward the outlet 22. (Col. 2, lines 55-58). Runnells further discloses that:

> The procedure normally followed in using the claimed syringe is to first position the syringe housing with the outlet end up and the magnification head 40 removed. Contrast solution is poured into the syringe housing and the head 40 is replaced. A tube is then attached to the outlet 22 of the syringe and the free end of the tube is submerged in contrast solution. Air is bled from the syringe by advancing the piston plate 14 toward the outlet 22. Additional contrast solution may then be drawn through the tube into the syringe housing by retracting the piston plate. The contents of the safety chamber 46 may then be viewed through the transparent wall 42 of the magnifying safety head. If bubbles are noted, the piston plate is advanced and retracted once more to expel the entrapped air and to replace the desired volume of contrast solution. The contents of the safety chamber are again viewed, and the piston plate may again be advanced and retracted as often as necessary until no bubbles are observed through the magnifying walls 42 of the head 40. (Col. 3, lines 1-20. *Emphasis Added.*)

Thus, Runnells discloses that the operator provides input, including observing for bubbles to determine if air bubbles are present, and providing the indication to advance based on the visual inspection for bubbles. Further, Runnells does not teach or suggest priming a tube connected to a syringe. Accordingly, Runnells teaches away from "automatically advancing, without operator input, the piston to prime the syringe and a tube connected to the syringe" of Applicants' invention of Claim 1.

Niehoff is directed to the injector including a plunger drive controller that has a locked mode in which motion, initially requested by pressing a manual movement

switch, will continue whether or not the operator continues pressing the switch, until the plunger drive reaches its fully-advanced or fully-retracted position. (Col 2, line 67 to col. 3, line 4.) Niehoff discloses allowing the operator to adjust the rate at which the plunger drive moves or accelerates and essentially moving the syringe based on a "locked mode" or by operator manual control (see col. 5, lines 1- 36). Further, Niehoff discloses storing an offset value representing the length of the extender. This length is utilized for the controller to determine the amount of contrast remaining in the syringe, andusing this value to avoid malfunction in the plunger drive controller (Col. 3, lines 48-61, thus Niehoff uses the offset value for a limited purpose. In fact, Niehoff is directed to controlling the plunger with operator required input to advance or retract the plunger, and thus does not teach alone or in combination with Runnells "automatically advancing, without operator input, the piston to prime the syringe and a tube connected to the syringe" of Applicants' invention of Claim 1.

Regarding Claim 8, Applicants' invention of Claim 8 has been amended and includes "sensing that the syringe is mounted on the injector; automatically determining based on the sensing whether the syringe is an empty syringe, a preloaded syringe or a prefilled syringe; and in response to sensing the syringe, automatically advancing the piston of the injector to engage the plunger of the syringe, wherein the automatically advancing and retracting of the piston is without operator input."

This novel feature of Applicants' invention includes that:

> the "auto engage" feature allows an injector to automatically advance the drive piston thereof to engage a syringe plunger upon installation or attachment of the syringe to the injector. In a preferred embodiment, the auto engage feature occurs without operator intervention. This feature is particularly useful for preloaded and prefilled syringes, which typically have plungers located at some position within the syringe barrel other than at the proximal and distal ends thereof, and plunger-forward syringes. In the case of prefilled syringes, the auto engage feature automatically connects the injector piston and syringe plunger for subsequent priming of the syringe (and associated tubing) and subsequent injection. For plunger-forward syringes, the auto engage feature engages the piston and plunger for subsequent retraction of the plunger for aspiration of fluid, such as contract media, into the syringe. (Specification, page 57, para 2).

However, Niehoff is directed to computer-controlled injector that requires steps that are entirely different that Applicants' invention. Namely, operator intervention of initiating movement of the plunger forward or reward is required for the driver to begin moving or change directions. If the syringe is an empty syringe, then Neihoff requires some input beyond just sensing that the syringe has been installed in the injector. The operator must provide manual input to begin movement of the plunger drive to position the plunger drive near the plunger (col. 5, lines 1-22). Thus, Niehoff does not teach or suggest automatic advancement and retracting, without operator input.

Further, Runnells et al does not disclose sensing of the syringe when mounted and automatically advancing the piston of the injector based on the sensing. Thus, neither Runnells or Niehoff, alone or in combination, teach or suggest Applicants' invention of Claim 8. Reconsideration is requested.

Regarding Claim 11, Claim 11 has been amended and includes subject matter similar to Claim 1 - "automatically advancing, without operator input, the piston to prime the syringe and a tube connected to the syringe, wherein the priming is based on a fluid volume of the tube." As discussed above, Runnells teaches that air is bled from a syringe, but requires operator involvement, including visual observation. In fact, Runnells is limited to requiring the observation of air bubbles in the bleeding of air from the syringe. (See Col. 3, lines 4-28). Additionally, Runnells does not teach that "the priming is based on a fluid volume of the tube" of Applicants' invention of Claim 11. Rather, Runnells teaches away from Applicants' invention by not only requiring operator input based on observation of air bubbles, but also entrapping air and retaining it within the safety chamber 46 (See Col. 3, lines 20-35). Further, Niehoff either alone or in combination, does not remedy the deficiencies of Runnells. Reconsideration of Claim 11 is requested.

Regarding Claim 14, claim 14 includes that the priming is based on a predetermined amount. Neither, Runnells nor Niehoff teach or suggest Applicants' invention. Accordingly, reconsideration of Claim 14 is requested.

Regarding Claims 15 and 17, Claims 15 and 17 are directed to "advancing the

piston during the step of retracting the piston to retract the plunger and aspirate fluid…" However, neither Runnells nor Niehoff teach or suggest this novel feature of Applicants' invention. Therefore, reconsideration is requested.

Claims 5, 6 10 and 14-16 depend, either directly or indirectly, from Claim 1, 8 and 11, which as discussed herein is believed to be allowable. Thus, Claims 5, 6, 10 and 14-16 are also believed to be allowable. Accordingly, reconsideration of Claims 1, 5, 6, 8, 10, 11 and 14-17 is respectfully requested.

In view of the above amendments and remarks, Applicants submit that the claims are in condition for allowance and the Examiner would be justified in allowing them.

Respectfully submitted,

Dated: March 20 , 2008

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